

REMARKS

In the Official Action, the Examiner rejected claims 1-22 and withdrew claims 23-27. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab et al. (U.S. Publication No. 2003/0036689, hereafter referred to as “the Diab reference”) in view of Chin et al. (U.S. Patent No. 6,018,673, hereafter referred to as “the Chin reference”) and further in view of Mortz (U.S. Patent No. 6,987,994, hereafter referred to as “the Mortz reference”). Applicants respectfully traverse the Examiner’s rejections.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (emphasis added). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 U.S.P.Q.2d.

1430 (Fed. Cir. 1990). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985).

In pulse oximetry, the calculation of oxygen saturation can be rendered inaccurate if venous pulsations are present. Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. Accordingly, the present application is directed to detecting the presence of venous *pulsations* so that a caregiver may be notified and take measures to preclude the presence of further venous pulsations, e.g., by tightening the sensor on the patient. As such, independent claim 1 recites, *inter alia*, “detecting the presence or absence of venous pulsation...and indicating the presence of venous pulsation to a caregiver if a venous pulsation is present.” Independent claim 13 recites, *inter alia*, “means for detecting the presence or absence of venous pulsation...and means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present.”

In sharp contrast, none of the references of record disclose this problem much less any way to address it. The Diab reference instead discloses a system where the venous *saturation* is quantified. Specifically, the Diab reference calculates an arterial saturation and a venous saturation. See Diab, Paragraph 395. To measure the venous saturation, the Diab reference uses

arterial saturation values and, thus, the venous saturation measurement appears to derive from arterial saturation measurements. *See id.* The Diab reference explains:

In order to obtain the venous saturation, the minimum arterial saturation value, of points that exhibit non-zero value, is selected rather than the maximum arterial saturation value. The saturation can be provided to the display 336.

Diab, Paragraph 395. Clearly, there is no discussion regarding the presence or absence of a venous *pulsation*, much less any discussion of how to remedy a situation when a venous pulsation is present. Furthermore, as correctly noted by the Examiner, the Diab reference clearly does not disclose that an indication of venous pulsation is provided to a caregiver for any reason.

Contrary to the Examiner's assertions, however, the Mortz reference fails to obviate the deficiencies of the Diab reference. Specifically, the Mortz patent fails to teach detecting the presence or absence of venous pulsation and indicating the presence of venous pulsation to a caregiver, as set forth in independent claims 1 and 13. The Examiner cites to the alarm generation circuit 108 of FIG. 1 of the Mortz reference as allegedly disclosing the step of indicating the presence of venous pulsation to a caregiver. Office Action, page 3. However, the alarm generation circuit 108 of the Mortz reference only indicates a data error condition. *See* Mortz, col. 5, lines 41-46. Specifically, the Mortz reference explains:

In addition, data processing circuit 107 detects anomalies in the input data stored in memory 106 and sets error codes which may be used to activate an alarm generation circuit 108 to produce an audible and/or visual alarm to user to indicate a data error condition.

Mortz, col. 5, lines 41-46. As such, there is absolutely no indication that the alarm generation circuit 108 responds to the detection of venous pulsation.

In fact, the Mortz reference apparently operates on the assumption that venous pulsations are not present. As mentioned above, sensors used with pulse oximeters are presumably secured to patients tightly enough to overcome venous pulsations, but not so tightly as to overcome the arterial pulsations sought to be measured. As illustrated in FIG. 8 of the Mortz reference, the non-pulsatile component of a signal represents the light remaining after absorption due to a combination of venous blood flow, tissue, bone, and constant arterial blood flow. Mortz, col. 5, lines 58-63. The small pulsatile component, however, is only caused by the light absorption due to the pulsatile *arterial* blood flow that is to be measured. *See* Mortz, col. 5, lines 58-63. Thus, the Mortz reference clearly operates under the presumption that the sensor is tight enough to overcome any venous *pulsations*. Therefore, Applicants respectfully assert that the Mortz reference at best discloses detection of arterial pulsations. Accordingly, the Mortz reference fails to obviate the deficiencies of the Diab reference with respect to detecting the presence or absence of venous pulsations and indicating the presence of venous pulsations to a caregiver.

The Chin reference fails to cure the deficiencies of the Diab reference and the Mortz reference, as described above. While the Chin reference does show Lissajous plots, the Chin reference does not disclose detecting the presence or absence of venous pulsation by using such plots and indicating the presence of venous pulsation to a caregiver, as set forth in independent claims 1 and 13. Therefore, the Chin reference fails to obviate the deficiencies of the Diab reference and the Mortz reference.

In conclusion, the Diab reference, the Mortz reference, and the Chin reference, taken alone or in hypothetical combination, do not disclose all of the elements of the independent claims 1 and 13. As such, Applicants respectfully request the withdrawal of the rejection of independent claims 1 and 13 under 35 U.S.C. § 103, as well as the rejection of all claims dependent thereon.

Conclusion

In view of the remarks set forth above, Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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